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DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,061

Applicant(s)

BACHUR ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/24/05, 6/27/05 and 10/18/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-74,76,77,79-89,91,92,94-108,110 and 111 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-74,76,77,79-89,91,92,94-108,110 and 111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/24/05&6/27/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 1/24/05 and 6/27/05 have been considered and made of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 79, 80, 82-84, 91 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Nix et al.(US 5,473,161).

The reference of Sussman et al. discloses a device and method of use for detection of the presence of biological activity in a sealed container utilizing infrared analysis of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 6, lines 25-33). The device includes a detector (17) and a signal analyzer (See column 6, lines 59-68, and Figures 5 and 6) to determine the concentration of the gas and/or whether the gas exists in the container. Also, the container of Sussman et al. is capable of optically transmitting the energy signal from the emitting device to the detector. With respect to the claimed plurality of containers and modules with a plurality of openings, the reference of Sussman et al. discloses the use of a module (track) with openings for holding a plurality of containers (See column 3, lines 49-61).

While the detection and signal analyzer of the reference of Sussman et al. is able to determine whether the monitored gas exists in the container, instant claim 79 requires that a laser is employed to generate the required energy. Specifically, the reference of Sussman et al.

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discloses the use of a Nicolet 5-MX FT-IR spectrophotometer for determining the concentration of carbon dioxide within the container which is indicative of the growth or presence of microorganisms within the container (See column 6, lines 59-68, and Figures 5 and 6).

The reference of Wrobel et al. first discloses that “Infrared absorption spectroscopy is a classical method for the detection and quantification determination of numerous gases and vapors” (See column 1, lines 10-12). The reference also discloses that some instruments for IR spectroscopy are inadequate due to narrow absorption linewidths of some gases (See column 1, lines 12-16). The reference of Wrobel et al. also discloses that the use of semiconductor diode lasers in the design of infrared spectrometers is advantageous because they are “tunable” over a wide range of wavelengths and because of their relative simplicity, efficiency and small size (See column 1, lines 21-26).

The reference of Noller discloses that it is known in the art to employ a laser diode when performing spectrophotometric analysis so as to avoid the need for a separate wavelength controller (See column 1, lines 48-66).

The reference of Veale discloses that the use of tunable diode lasers is advantageous over FTIR spectroscopy because the tunable diode laser has a higher sensitivity than FTIR spectroscopy (See column 1, lines 16-34).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention to employ an infrared absorption spectroscopy device that employs a laser diode as suggested by any of the references of Wrobel et al. or Noller or Veale in the system of the primary reference of Sussman et al. for the known and expected result of providing an art recognized means for performing classical infrared absorption spectroscopy

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while providing the benefits associated with the use of a tunable semiconductor diode laser device.

Claim 79 further differs by reciting that a single wavelength of 2.004 micrometers is employed for detecting carbon dioxide within the container.

The reference of Nix et al. discloses that it is known in the art to employ a wavenumber of 4992 (approximately 2.004 micrometers) when detecting for the presence of carbon dioxide within a sealed vessel that can be made of glass or plastic (See column 2, lines 37-58).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a wavelength of approximately 2.004 when detecting for the presence of carbon dioxide within the culture vessel of Sussman et al. for the known and expected result of providing an art recognized means for detecting the presence of carbon dioxide that is independent of the specific material of the transparent container (See column 2, lines 45-48).

With respect to claim 80, the laser suggested by the prior art would be a monomodal laser.

With respect to claims 82 and 83, the system would be capable of determining the presence and/or concentration of carbon dioxide in the container.

With respect to claim 84, the tunable laser devices suggested by the prior art all include spectrography devices for analyzing the detected portion of the radiation.

With respect to claim 91, when detecting a plurality of containers, it would have been obvious to one of ordinary skill in the art to provide a plurality of lasers and sensors, thus eliminating the need to move the containers between a single sensor station.

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With respect to claim 92, the system suggested by the prior art above is capable of being used with a sample vial with a neck portion.

6. Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Nix et al.(US 5,473,161) and taken further in view of Waters (US 4,952,498) and Brace (US 5,614,718).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Nix et al. has been discussed above.

The above claims differ by reciting that the IR spectrometry provides an indication of pressure within the culture vessel.

The reference of Waters discloses that a change of pressure within a culture vessel is indicative of the presence of a gas-generating microorganism (See the abstract).

The reference of Brace discloses that it is known in the art to correlate the results of the detection of carbon dioxide concentration using IR spectrometry to pressure of carbon dioxide within the sealed vessel (See column 5, lines 8-25).

In view of these references, it would have been obvious to one of ordinary skill in the art to employ the IR spectrometry results of the primary reference as a means to determine the pressure and/or change of pressure within the sealed culture vessel over time as an alternative means recognized in the art for indicating the presence of a gas-generating microorganism within the vessel.

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7. Claims 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Nix et al.(US 5,473,161) and taken further in view of Carr et al.(US 5,888,825).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Nix et al. has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

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8. Claims 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Nix et al.(US 5,473,161) and taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Nix et al. has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

9. Claims 63-65, 67-69, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Wong (US 4,730,112).

The reference of Sussman et al. discloses a device and method of use for detection of the presence of biological activity in a sealed container utilizing infrared analysis of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 6, lines 25-33). The device includes a detector (17) and a signal analyzer (See column 6, lines 59-68, and Figures 5 and 6) to determine the concentration of the gas and/or whether the gas exists in the container. Also, the container of Sussman et al. is capable of optically transmitting the energy signal from the emitting device to the detector. With respect to the claimed plurality of containers and modules with a plurality of openings, the reference of Sussman et al. discloses the use of a module (track) with openings for holding a plurality of containers (See column 3, lines 49-61).

While the detection and signal analyzer of the reference of Sussman et al. is able to determine whether the monitored gas exists in the container, instant claim 63 requires that a laser is employed to generate the required energy. Specifically, the reference of Sussman et al. discloses the use of a Nicolet 5-MX FT-IR spectrophotometer for determining the concentration of carbon dioxide within the container which is indicative of the growth or presence of microorganisms within the container (See column 6, lines 59-68, and Figures 5 and 6).

The reference of Wrobel et al. first discloses that "Infrared absorption spectroscopy is a classical method for the detection and quantification determination of numerous gases and vapors" (See column 1, lines 10-12). The reference also discloses that some instruments for IR spectroscopy are inadequate due to narrow absorption linewidths of some gases (See column 1,

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lines 12-16). The reference of Wrobel et al. also discloses that the use of semiconductor diode lasers in the design of infrared spectrometers is advantageous because they are “tunable” over a wide range of wavelengths and because of their relative simplicity, efficiency and small size (See column 1, lines 21-26).

The reference of Noller discloses that it is known in the art to employ a laser diode when performing spectrophotometric analysis so as to avoid the need for a separate wavelength controller (See column 1, lines 48-66).

The reference of Veale discloses that the use of tunable diode lasers is advantageous over FTIR spectroscopy because the tunable diode laser has a higher sensitivity than FTIR spectroscopy (See column 1, lines 16-34).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention to employ an infrared absorption spectroscopy device that employs a laser diode as suggested by any of the references of Wrobel et al. or Noller or Veale in the system of the primary reference of Sussman et al. for the known and expected result of providing an art recognized means for performing classical infrared absorption spectroscopy while providing the benefits associated with the use of a tunable semiconductor diode laser device.

Claim 63 further differs by reciting that other gas components other than carbon dioxide are detected by the detection system. Specifically, the laser emits radiation at a wavelength at which oxygen absorbs radiation.

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The reference of Sussman et al. discloses that while the metabolic product of interest in the examples is carbon dioxide, other metabolically formed gases may be detected (See column 6, lines 25-34).

The reference of Ahnell et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See column 7, lines 34-48).

The reference of Wong discloses that it is known in the art to employ diode lasers to detect oxygen within a gas sample (See column 5, lines 12-59).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide, for example oxygen, within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel. The use of a diode laser system as disclosed by Wong would provide an art recognized system for detecting oxygen while providing the benefits associated with a diode laser verses an FTIR system of Sussman as discussed previously.

With respect to claim 64, the laser suggested by the prior art would be a monomodal laser.

With respect to claim 65, the reference of Wong discloses using a single wavelength of approximately 761.5 nanometers (See column 2, line 65, to column 3, line 13).

With respect to claims 67 and 68, the system would be capable of determining the presence and/or concentration of carbon dioxide in the container.

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With respect to claim 69, the tunable laser devices suggested by the prior art all include spectrography devices for analyzing the detected portion of the radiation.

With respect to claim 76, when detecting a plurality of containers, it would have been obvious to one of ordinary skill in the art to provide a plurality of lasers and sensors, thus eliminating the need to move the containers between a single sensor station.

With respect to claim 77, the system suggested by the prior art above is capable of being used with a sample vial with a neck portion.

10. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Wong (US 4,730,112) and taken further in view of Waters (US 4,952,498) and Brace (US 5,614,718).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Wong has been discussed above.

The above claim differs by reciting that the IR spectrometry provides an indication of pressure within the culture vessel.

The reference of Waters discloses that a change of pressure within a culture vessel is indicative of the presence of a gas-generating microorganism (See the abstract).

The reference of Brace discloses that it is known in the art to correlate the results of the detection of carbon dioxide concentration using IR spectrometry to pressure of carbon dioxide within the sealed vessel (See column 5, lines 8-25).

In view of these references, it would have been obvious to one of ordinary skill in the art to employ the IR spectrometry results of the primary reference as a means to determine the pressure and/or change of pressure within the sealed culture vessel over time as an alternative means recognized in the art for indicating the presence of a gas-generating microorganism within the vessel.

11. Claims 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Wong (US 4,730,112) and taken further in view of Carr et al.(US 5,888,825).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Wong has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

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In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

12. Claims 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Wong (US 4,730,112) and taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Wong has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation

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environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

13. Claims 94-99, 101-103, 110 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Allen (Measurement Science and Technology).

The reference of Sussman et al. discloses a device and method of use for detection of the presence of biological activity in a sealed container utilizing infrared analysis of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 6, lines 25-33). The device includes a detector (17) and a signal analyzer (See column 6, lines 59-68, and Figures 5 and 6) to determine the concentration of the gas and/or whether the gas exists in the container. Also, the container of Sussman et al. is capable of optically transmitting the energy signal from the emitting device to the detector. With respect to the claimed plurality of containers and modules with a plurality of openings, the reference of Sussman et al. discloses the use of a module (track) with openings for holding a plurality of containers (See column 3, lines 49-61).

While the detection and signal analyzer of the reference of Sussman et al. is able to determine whether the monitored gas is exists in the container, instant claim 94 requires that a laser is employed to generate the required energy. Specifically, the reference of Sussman et al.

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discloses the use of a Nicolet 5-MX FT-IR spectrophotometer for determining the concentration of carbon dioxide within the container which is indicative of the growth or presence of microorganisms within the container (See column 6, lines 59-68, and Figures 5 and 6).

The reference of Wrobel et al. first discloses that “Infrared absorption spectroscopy is a classical method for the detection and quantification determination of numerous gases and vapors” (See column 1, lines 10-12). The reference also discloses that some instruments for IR spectroscopy are inadequate due to narrow absorption linewidths of some gases (See column 1, lines 12-16). The reference of Wrobel et al. also discloses that the use of semiconductor diode lasers in the design of infrared spectrometers is advantageous because they are “tunable” over a wide range of wavelengths and because of their relative simplicity, efficiency and small size (See column 1, lines 21-26).

The reference of Noller discloses that it is known in the art to employ a laser diode when performing spectrophotometric analysis so as to avoid the need for a separate wavelength controller (See column 1, lines 48-66).

The reference of Veale discloses that the use of tunable diode lasers is advantageous over FTIR spectroscopy because the tunable diode laser has a higher sensitivity than FTIR spectroscopy (See column 1, lines 16-34).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention to employ an infrared absorption spectroscopy device that employs a laser diode as suggested by any of the references of Wrobel et al. or Noller or Veale in the system of the primary reference of Sussman et al. for the known and expected result of providing an art recognized means for performing classical infrared absorption spectroscopy

while providing the benefits associated with the use of a tunable semiconductor diode laser device.

Claim 94 further differs by reciting that other gas components other than carbon dioxide are detected by the detection system. Specifically, the laser emits radiation at a wavelength at which ammonia, hydrogen sulfide, methane or sulfur dioxide absorbs radiation.

The reference of Sussman et al. discloses that while the metabolic product of interest in the examples is carbon dioxide, other metabolically formed gases may be detected (See column 6, lines 25-34).

The reference of Ahnell et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See column 7, lines 34-48).

The reference of Allen discloses that it is known in the art to employ diode lasers to detect gases including ammonia, methane, hydrogen sulfide and sulfur dioxide within a gas sample (See page 14, first full paragraph and page 33, lines 8-11).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide, for example any of the gases disclosed by the reference of Ahnell, within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel. The use of any of the diode laser systems as discussed by Allen would provide art recognized diode lasers capable of detecting the gases suggested by Ahnell while providing the benefits associated with a diode laser verses an FTIR system of Sussman as discussed previously.

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With respect to claim 95, the laser suggested by the prior art would be a monomodal laser.

With respect to claims 96-99, the reference of Allen discloses using diode lasers of different wavelengths based merely on the specific gas to be detected. The disclosed diode lasers include wavelengths encompassed by those of claims 96-99 (See pages 14-16 and 33). The specific wavelength employed would have been well within the purview of one having ordinary skill in the art based merely on the specific gas component that is desired to be detected within the gas space.

With respect to claims 101 and 102, the system would be capable of determining the presence and/or concentration of carbon dioxide in the container.

With respect to claim 103, the tunable laser devices suggested by the prior art all include spectrography devices for analyzing the detected portion of the radiation.

With respect to claim 110, when detecting a plurality of containers, it would have been obvious to one of ordinary skill in the art to provide a plurality of lasers and sensors, thus eliminating the need to move the containers between a single sensor station.

With respect to claim 111, the system suggested by the prior art above is capable of being used with a sample vial with a neck portion.

14. Claim 100 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Allen (Measurement Science and Technology) and taken further in view of Waters (US 4,952,498) and Brace (US 5,614,718).

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The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Allen has been discussed above.

The above claim differs by reciting that the IR spectrometry provides an indication of pressure within the culture vessel.

The reference of Waters discloses that a change of pressure within a culture vessel is indicative of the presence of a gas-generating microorganism (See the abstract).

The reference of Brace discloses that it is known in the art to correlate the results of the detection of carbon dioxide concentration using IR spectrometry to pressure of carbon dioxide within the sealed vessel (See column 5, lines 8-25).

In view of these references, it would have been obvious to one of ordinary skill in the art to employ the IR spectrometry results of the primary reference as a means to determine the pressure and/or change of pressure within the sealed culture vessel over time as an alternative means recognized in the art for indicating the presence of a gas-generating microorganism within the vessel.

15. Claims 104-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Allen (Measurement Science and Technology) and taken further in view of Carr et al.(US 5,888,825).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Allen has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

16. Claims 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Allen (Measurement Science and Technology) and taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Allen has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

Response to Amendment

17. The declaration filed on 6/27/05 under 37 CFR 1.131 has been considered but is ineffective to overcome the Veale (US 6,639,678) reference.

The declaration has been determined to be ineffective for the following reasons:

- i) Not signed by all of the inventors.
- ii) Fails to establish that the invention was reduced to practice in the United States or a NAFTA or WTO member country.
- iii) The evidence of conception and reduction to practice is not commensurate in scope with the instant claims. Note the claims recite a module with openings and a plurality of vessels which is not shown in the evidence provided.

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- iv) The evidence does not establish that the system was reduced to practice and worked for its intended purpose. The only evidence submitted appears to be a paper written about the system. The evidence does not include pictures of the system and/or experimentation evidence with respect to making and using the system.

Response to Arguments

18. With respect to the rejection of claims 63-65, 67-69, 75 and 77 under 35 USC 102(b) over the reference of Wong, Applicant's amendments to the claims and associated comments (See page 9 of the response filed 6/27/05) are persuasive to overcome the 35 USC 102(b) rejection.

19. With respect to the rejection of claims 63-65, 67-69 and 75-78 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Wong, Applicant argues (See pages 9-11 of the response filed 6/27/05) that the rejection is improper because there is no motivation to combine the references in the manner asserted by the Examiner. Applicant also argues that even if the references are combined, the teachings are so disparate that it is not apparent what one skilled in the art would have done with the combination in view of the lack of focus on oxygen in the majority of the references.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the Examiner is of

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the position that the totality of the references would have provided one of ordinary skill in the art to arrive at the instantly claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner maintains that the teachings of any of the references of Wrobel, Noller or Veale would have provided one of ordinary skill in the art with ample motivation to employ a infrared absorption spectroscopy device that employs a laser diode device in place of the system employed by Sussman et al. for the known and expected advantages associated with the use of tunable semiconductor diode laser devices. With respect for the motivation for the detection of oxygen rather than carbon dioxide, the reference of Sussman clearly suggests that other gases can be detected (See column 6, lines 25-34). The reference of Ahnell et al. clearly suggests that oxygen is a desirable gas to be detected when observing the metabolic gas of a culture vessel (See column 7, lines 34-48). Clearly one of ordinary skill in the art when presented with the disclosures of Sussman and Ahnell et al. would have been motivated to detect metabolic gases including oxygen. The reference of Wong was merely cited as a prior art teaching to evidence that laser diodes such as those disclosed by the references of Wrobel, Noller or Veale are known for detecting oxygen.

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In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Additionally note the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

With respect to Applicant's comment that the prior art does not direct one skilled in the art to the specific wavelength of 761.5 nanometers, the Examiner points out that the reference of Wong suggests to one of ordinary skill in the art that an absorption band for oxygen exists at around 760 nanometer (See column 2, line 65, to column 3, line 13).

Finally the Examiner maintains that the reference of Veale is a valid reference in view of the deficiencies discussed with respect to the 37 CFR 1.131 declaration.

20. With respect to the rejection of claim 66 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Wong and taken further in view of Waters and Brace, Applicant argues (See page 12 of the response

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filed 6/27/05) that the disclosures of the references of Waters and Brace fail to remedy the shortcomings of the previously discussed combination of references.

In response, the references of Waters and Brace were merely relied upon to address the additional claim limitations of claim 66. The Examiner maintains that the combination of the references of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Wong is proper for the reasons set forth previously.

21. With respect to the rejection of claims 70-72 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Wong and taken further in view of Carr et al., Applicant argues (See pages 12-13 of the response filed 6/27/05) that the disclosure of the reference of Carr et al. fails to remedy the shortcomings of the previously discussed combination of references.

In response, the reference of Carr et al. was merely relied upon to address the additional claim limitations of claims 70-72. The Examiner maintains that the combination of the references of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Wong is proper for the reasons set forth previously.

22. With respect to the rejection of claims 73 and 74 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Wong and taken further in view of Berndt et al., Applicant argues (See page 13 of the response filed 6/27/05) that the disclosure of the reference of Berndt et al. fails to remedy the shortcomings of the previously discussed combination of references.

In response, the reference of Berndt et al. was merely relied upon to address the additional claim limitations of claims 73 and 74. The Examiner maintains that the combination of the references of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Wong is proper for the reasons set forth previously.

23. With respect to the rejection of claims 79, 82, 84, 90 and 92 under 35 USC 102(b) over the reference of Wrobel, Applicant's amendments to the claims and associated comments (See page 9 of the response filed 6/27/05) are persuasive to overcome the 35 USC 102(b) rejection.

24. With respect to the rejection of claims 79, 80, 82-84 and 90-93 under 35 USC 103 over the combination of the references of Sussman in view of Wrobel or Noller or Veale taken further in view of Nix, Applicant argues (See pages 14-15 of the response filed 6/27/05) that the rejection is improper because there is no motivation to combine the references in the manner asserted by the Examiner. Applicant also argues that even if the references are combined, the teachings are so disparate that it is not apparent what one skilled in the art would have done with the combination since the references all deal with different wavelengths for the detection of carbon dioxide.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the Examiner is of

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the position that the totality of the references would have provided one of ordinary skill in the art to arrive at the instantly claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner maintains that the teachings of any of the references of Wrobel, Noller or Veale would have provided one of ordinary skill in the art with ample motivation to employ a infrared absorption spectroscopy device that employs a laser diode device in place of the system employed by Sussman et al. for the known and expected advantages associated with the use of tunable semiconductor diode laser devices. With respect to Applicant's comments concerning the obviousness of the specific wavelength for the detection of carbon dioxide, while the reference of Sussman and Wrobel may suggest 4.26-4.28 micrometers, the reference of Nix clearly discloses that the claimed wavelength is an additional wavelength recognized in the art for detecting carbon dioxide in a sealed vessel. In view of this teaching, one of ordinary skill in the art in the absence of a showing of criticality and/or unexpected results would have been motivated to employ the wavelength of Nix for the known and expected result of providing an alternative wavelength recognized in the art to detect carbon dioxide. Furthermore, the reference of Nix even recites that the disclosed wavelength provides advantages over other known wavelengths (See column 2, lines 37-58).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Additionally note the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Finally the Examiner maintains that the reference of Veale is a valid reference in view of the deficiencies discussed with respect to the 37 CFR 1.131 declaration.

25. With respect to the rejection of claim 81 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view Nix and taken further in view of Waters and Brace, Applicant argues (See page 12 of the response filed 6/27/05) that the disclosures of the references of Waters and Brace fail to remedy the shortcomings of the previously discussed combination of references.

In response, the references of Waters and Brace were merely relied upon to address the additional claim limitations of claim 66. The Examiner maintains that the combination of the

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references of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Nix is proper for the reasons set forth previously.

26. With respect to the rejection of claims 85-87 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Nix and taken further in view of Carr et al., Applicant argues (See pages 12-13 of the response filed 6/27/05) that the disclosure of the reference of Carr et al. fails to remedy the shortcomings of the previously discussed combination of references.

In response, the reference of Carr et al. was merely relied upon to address the additional claim limitations of claims 70-72. The Examiner maintains that the combination of the references of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Nix is proper for the reasons set forth previously.

27. With respect to the rejection of claims 88 and 89 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Nix and taken further in view of Berndt et al., Applicant argues (See page 13 of the response filed 6/27/05) that the disclosure of the reference of Berndt et al. fails to remedy the shortcomings of the previously discussed combination of references.

In response, the reference of Berndt et al. was merely relied upon to address the additional claim limitations of claims 73 and 74. The Examiner maintains that the combination of the references of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Nix is proper for the reasons set forth previously.

28. With respect to the rejection of claims 94-99, 101-103 and 109-112 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Allen, Applicant argues (See pages 17-19 of the response filed 6/27/05) that the rejection is improper because there is no motivation to combine the references in the manner asserted by the Examiner. Applicant also argues that even if the references are combined, the teachings are so disparate that it is not apparent what one skilled in the art would have done with the combination in view of the lack of focus on the recited gases in the references.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the Examiner is of the position that the totality of the references would have provided one of ordinary skill in the art to arrive at the instantly claimed invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner maintains that the teachings of any of the references of Wrobel, Noller or Veale would have provided one of ordinary skill in the art with ample motivation to employ a

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infrared absorption spectroscopy device that employs a laser diode device in place of the system employed by Sussman et al. for the known and expected advantages associated with the use of tunable semiconductor diode laser devices. With respect for the motivation for the detection of gases other than carbon dioxide, the reference of Sussman clearly suggests that other gases can be detected (See column 6, lines 25-34). The reference of Ahnell et al. clearly suggests that a number of different gases are known and would be desirable for detection within a culture vessel (See column 7, lines 34-48). Clearly one of ordinary skill in the art when presented with the disclosures of Sussman and Ahnell et al. would have been motivated to detect metabolic gases including oxygen. The reference of Allen was merely cited as a prior art teaching to evidence that laser diodes such as those disclosed by the references of Wrobel, Noller or Veale are known for detecting the other gases suggested by the reference of Ahnell et al..

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Additionally note the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the

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test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

With respect to Applicant's comment that the prior art does not direct one skilled in the art to the specific wavelengths of claims 96-99, the Examiner points out that the reference of Allen suggests to one of ordinary skill in the art that diode lasers including the claimed wavelengths are known and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum wavelength based merely on the specific gas to be detected.

Finally the Examiner maintains that the reference of Veale is a valid reference in view of the deficiencies discussed with respect to the 37 CFR 1.131 declaration.

29. With respect to the rejection of claim 100 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view Ahnell and Allen and taken further in view of Waters and Brace, Applicant argues (See page 20 of the response filed 6/27/05) that the disclosures of the references of Waters and Brace fail to remedy the shortcomings of the previously discussed combination of references.

In response, the references of Waters and Brace were merely relied upon to address the additional claim limitations of claim 66. The Examiner maintains that the combination of the references of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Allen is proper for the reasons set forth previously.

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30. With respect to the rejection of claims 104-106 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Allen and taken further in view of Carr et al., Applicant argues (See pages 20-21 of the response filed 6/27/05) that the disclosure of the reference of Carr et al. fails to remedy the shortcomings of the previously discussed combination of references.

In response, the reference of Carr et al. was merely relied upon to address the additional claim limitations of claims 70-72. The Examiner maintains that the combination of the references of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Allen is proper for the reasons set forth previously.

31. With respect to the rejection of claims 107 and 108 under 35 USC 103 over the combination of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Allen and taken further in view of Berndt et al., Applicant argues (See page 21 of the response filed 6/27/05) that the disclosure of the reference of Berndt et al. fails to remedy the shortcomings of the previously discussed combination of references.

In response, the reference of Berndt et al. was merely relied upon to address the additional claim limitations of claims 73 and 74. The Examiner maintains that the combination of the references of Sussman in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell and Allen is proper for the reasons set forth previously.

Conclusion

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32. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB